

## REMARKS

Claims 1, 2, 4, 5 and 15-17 were pending at the time of the electronic mailing of the outstanding Office Action. By this response, no claims have been amended, added or cancelled.

In the Office Action of 19 February 2010, claims 1-2, 4 and 15 were rejected under 35 U.S.C. § 102(e), as being anticipated by U.S. Patent Pub. No. US 2003/0083646 to Sirhan et al. (hereinafter "Sirhan"). Under 35 U.S.C. § 103(a), claims 16-17 were rejected as being obvious over Sirhan in view of U.S. Pat. No. 5,972,027 to Johnson (hereinafter "Johnson").

In the Office Action, Sirhan was cited as providing a stent with a coating system comprising one or more polymer carriers and at least one pharmaceutically active substance, wherein the elution of the pharmaceutically active substance varies in the longitudinal direction of the stent. Paragraph 34 of Sirhan was cited as providing "areas (e.g., distal and proximal ends of the device) having variable thickness of both the source and the rate-controlling element to allow for slower or faster release." Paragraph 135 of Sirhan (which describes the embodiment shown in Fig. 9) was also cited as providing variable delivery of a therapeutic substance. Furthermore, paragraphs 40 and 45-46 were cited as indicating that degradation behavior of the carrier can serve to differentiate the local elution characteristics. However, the Applicants find no teaching or suggestion of the degradation behavior of the first polymer carrier differing from a degradation behavior of the second polymer carrier, as recited in claim 1. To anticipate a claim, a reference must teach all elements of the claim (MPEP § 2131). Therefore, because Sirhan does not provide all the elements of claims 1-2, 4 and 15, the Applicants maintain that Sirhan does not anticipate these claims. Withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

Claims 16-17 were rejected under 35 U.S.C. § 103(a) as being obvious over Sirhan in view of Johnson. To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. There must also be a reasonable expectation of success and the prior art reference or references must teach or suggest all of the claim limitations. (MPEP § 2143.)

Sirhan was alleged to provide the elements of the claims with the exception of the teaching of a concentration of drug greater adjacent the face surfaces than the middle with a second drug with a greater concentration in the middle than at the face surfaces. Johnson was relied upon for such a teaching. However, as stated in a previous response, Johnson provides different concentrations of a drug in different areas of the stent based on the porosity of the stent material itself, not on the degradation behavior of a polymer. In contrast, the claimed invention relies on the degradation behavior of a polymer to release the drug or drugs, not on the presence or size of pores in the structure. Johnson provides no indication that degradation plays any role in the release of a therapeutic agent.

The proposed combination of Sirhan with Johnson would change a principle of operation of Johnson and is therefore impermissible under MPEP 2143.01. As also stated previously, the combination of the teachings of the cited references with the need to simultaneously change a principle of operation of one of those references to arrive at the claimed invention indicates that the proposed combination is nonobvious. In other words, the need to change a principle of operation of one prior device when making a combination with another device to arrive at the claimed invention indicates that the combined teachings would not have suggested the present invention to one of ordinary skill in the art. Therefore, claims 16-17 patentably distinguish over

Sirhan and Johnson. Withdrawal of the rejection of claim 16-17 under 35 U.S.C. § 103(a) is respectfully requested.

The Applicants maintain that the pending claims distinguish over the cited prior art and are in condition for allowance. The issuance of a Notice of Allowance is respectfully requested.

The outstanding Office action was transmitted on 19 February 2010. The Examiner set a shortened statutory period for reply of 3 months from the mailing date. Therefore, no petition for an extension of time is believed to be required with the filing of this response, and this response should be treated as being filed within two months of the mailing date of the Final Office Action for purposes of calculating an extension fee due after the issuance of any subsequent advisory action under 37 C.F.R. 1.136(a). Nevertheless, the Applicants hereby make a conditional petition for an extension of time for response in the event that such a petition is required. No fees are believed to be due with this response. However, in the event that a fee for the filing of his response is insufficient, the Commissioner is authorized to charge any fee deficiency or to credit any overpayment to Deposit Account 15-0450.

Respectfully submitted,

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